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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/723,499  | 11/25/2003  | Keith Rosiello       | 18405-129           | 8935             |
| 48329   | 7590        | 09/13/2005           | EXAMINER            |                  |
| FOLEY & LARDNER LLP<br>111 HUNTINGTON AVENUE<br>26TH FLOOR<br>BOSTON, MA 02199-7610 |             |                      | SORKIN, DAVID L     |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1723                |                  |

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/723,499 | <b>Applicant(s)</b><br>ROSIELLO ET AL. |  |
|                              | <b>Examiner</b><br>David L. Sorkin   | <b>Art Unit</b><br>1723                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 July 2005.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.  
     4a) Of the above claim(s) 39-48 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-38 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12 March 2004</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-38, drawn to a bag, a centrifuge and related methods, classified in class 494, subclass 45.
  - II. Claims 39-48, drawn to a hub with channels, classified in class 138, subclass 111.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because, though a hub is mentioned in some of the claims of group I, the hub of group I does not require a channel. The subcombination hub has separate utility such as for mounting a pneumatic tire.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with John M. Garvey on 02 September 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-38. Affirmation of this election must be made by applicant in replying to this Office action. Claims 39-48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

8. Figures 4 and 5 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. Fig. 4 is essentially identical to Fig. 10 of US 2002/0107131 while Fig. 5 is essentially identical to Fig. 9 of US 2002/0107131 as well as Fig. 3 of WO 01/30505. Any other figures which solely depict prior art should be so labeled. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing

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figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

9. Claim 35 should end with a period.
10. Claim 31 is a substantial duplicate of claim 30 and will be objected to if claim 30 is found allowable.

### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-6, 11, 13-18, 24-29 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Drucker (US 3,675,846). Regarding claims 1,13 and 24, Drucker ('846) discloses a bag (81) (as well as a centrifuge comprising the bag) having a central opening which includes an integrally formed first mating portion mating with a corresponding second mating portion (55a,55b) of a hub (55) (see Fig. 3). Regarding claims 2, 14 and 25, the first mating portion comprises an integrally molded radial barrier (see Fig. 3, near 55b). Regarding claim 3,15, and 26, the first mating portion comprises one or more recesses (see Fig. 3). Regarding claim 4, 16, and 27 the first mating portion comprises one or more raised areas (see Fig. 3). Regarding claims 5, 17 and 28, the radial barrier comprises a circumferential ring of raised material (see Fig.

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3). Regarding claim 6, 18 and 29, the radial barrier comprises a circumferential recess (see Fig. 3). Regarding claim 11, the manner in which the bag is intended to be used is not germane to the patentability of the bag. Regarding claim 34, Drucker ('846) discloses a method of sealing a centrifuge bag to a hub comprising providing a bag (81), for use in centrifugal processing, wherein the bag comprises a substantially circular enclosure having an opening; and providing a hub (55) having a second mating portion (55a, 55b) corresponding to the first mating portion; placing the hub within the opening; and mating the first mating portion with the second mating portion (see Fig. 3; col. 2, lines 49-60).

13. Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Mercier (US 4,610,369). Regarding claims 1 and 13, Mercier ('369) discloses a bag (33) comprising a substantially circular enclosure having a central opening, wherein the central opening includes an integrally formed first mating portion (39) mating with a corresponding second mating portion of a hub (27). Regarding claims 2 and 14, the first mating portion comprises an integrally molded radial barrier (see Fig. 2, 3, 5 and 6). Regarding claims 3, 9, 15 and 21, the first mating portion comprises one or more recesses formed adjacent the opening (see Fig. 2, 3, 5 and 6). Regarding claims 4, 10, 16 and 22, the first mating portion comprises one or more raised areas formed adjacent the opening (see Fig. 2, 3, 5 and 6). Regarding claims 5 and 17, the radial barrier comprises a circumferential ring of raised material (see Fig. 2, 3, 5 and 6). Regarding claims 6 and 18, the radial barrier comprises a circumferential recess (see Fig. 2, 3, 5 and 6). Regarding claims 7 and 19, the bag includes a first side and second side, each

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side having a respective opening (see Fig. 2, 3, 5 and 6). Regarding claims 8 and 20, each side includes a first mating portion (see Fig. 2, 3, 5 and 6). Regarding claim 11, the manner in which the bag is intended to be used is not germane to the patentability of the bag. Regarding claims 12 and 23, the bag further comprises at least one weld ring having a central opening for receiving a first side of the hub and a surface positioned adjacent the first side of the bag proximate the opening of the first side (see Fig. 3).

14. Claims 1-29 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorgensen et al. (US 2002/0107131). Regarding claims 1, 13 and 24, Jorgensen ('131) discloses a bag (10, 50, 94, or 96) (as well as a centrifuge comprising the bag) comprising a substantially circular enclosure having a central opening (such as 11 or 51), wherein the central opening includes an integrally formed first mating portion mating with a corresponding second mating portion of a hub (20, 60, 104). See [0043]. Regarding claims 2, 14, and 25, the first mating portion comprises an integrally molded radial barrier (see especially Fig. 1). Regarding claims 3, 9, 15, 21, and 26, the first mating portion comprises one or more recesses formed adjacent the opening (see especially Fig. 1). Regarding claims 4, 10, 16, 22 and 27 the first mating portion comprises one or more raised areas formed adjacent the opening (see especially Fig. 1). Regarding claims 5, 17 and 28, the radial barrier comprises a circumferential ring of raised material (see especially Fig. 1). Regarding claims 6, 18 and 29, the radial barrier comprises a circumferential recess (see especially Fig. 1). Regarding claims 7 and 19, the bag includes a first side and second side, each side having a respective opening

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(see Fig. 1, 3, 7 and 11). Regarding claims 8 and 20, each side includes a first mating portion (see Fig. 1, 3, 7 and 11). Regarding claim 11, the manner in which the bag is intended to be used is not germane to the patentability of the bag. Regarding claims 12 and 23, the bag further comprises at least one weld ring (30, 40, 70, 80, 100 or 102) having a central opening for receiving a first side of the hub and a surface positioned adjacent the first side of the bag proximate the opening of the first side. Regarding claim 34, Jorgensen ('131) discloses a method of sealing a centrifuge bag to a hub comprising providing a bag (10, 50, 94 or 96) for use in centrifugal processing, wherein the bag comprises a substantially circular enclosure having a central opening (such as 11 or 51), wherein the central opening has a first mating portion (see Fig. 1); and providing a hub (20, 60 or 104) having a second portion corresponding to the first mating portion; placing the hub with in the opening; and mating the first mating portion with the second mating portion (see [0043], [0050], Figs. 1-8 and 11).

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. (US 2002/0107131). The method of Jorgensen was discussed above with regard to claim 34. While the verb "welding" is not expressly used by the reference, "weld rings" are extensively discussed (see [0047] and [0050]). The



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discussion of "weld rings" would have suggested welding, either with heat or with solvent, to one of ordinary skill in the art.

17. Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen et al. (US 2002/0107131) in view of Schlutz (US 3,982,691). Jorgensen ('131) discloses a method of sealing a centrifuge bag to a hub comprising providing a bag (10, 50, 94 or 96) for use in centrifugal processing, wherein the bag comprises a substantially circular enclosure having a central opening (such as 11 or 51), wherein the central opening has a first mating portion (see Fig. 1); and providing a hub (20, 60 or 104) having a second portion corresponding to the first mating portion; placing the hub with in the opening; and mating the first mating portion with the second mating portion (see [0043], [0050], Figs. 1-8 and 11). Use of adhesive is not explicitly disclosed. Schlutz ('691) teaches joining components of a centrifuge bag assembly using adhesive (see col. 12, lines 1-9). It would have been obvious to one of ordinary skill in the art to have joined the portions of Jorgensen ('131) using adhesive, because, since Jorgensen ('131) explains that joining is required but does not detail exactly how, one would look to prior art methods of joining such as those of Schlutz ('691), col. 12, lines 1-9.

### ***Conclusion***


18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 571-272-1148. The examiner can normally be reached on 9:00 -5:30 Mon.-Fri..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
David L. Sorkin  
Primary Examiner  
Art Unit 1723

DLS